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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,793	03/14/2007	James Robert Bostwick	101218-1P US	6758

22466 7590 03/24/2009

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,793	BOSTWICK ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/6*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence alignment, 2 pages*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on January 21, 2009 is acknowledged. However, since Applicant did not present any arguments to traverse the restriction, response to restriction requirements is considered as election without traverse. MPEP 818.03(a).

The requirement is deemed proper and is therefore made FINAL.

2. Claims 1-6 and 9-11 are pending in the instant patent application.

Claims 1-6 and 9-11 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 9 and 11 are vague and indefinite as being drawn to methods for producing a polypeptide by culturing a recombinant cell. One skilled in the art readily appreciates that any cell expresses a plurality of polypeptides and therefore the polypeptides expressed by the cell encompassed by the instant claims are not limited to the amino acid of SEQ ID NO: 2. Thus, it is not obvious as method of producing what polypeptide is indented by the

claims. Amendment to recite polypeptide identified by a SEQ ID NO: would obviate this ground of rejection.

6. Claim 10 is indefinite as being dependent from an indefinite claim.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are

"useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecule encoding a protein of as yet undetermined function or biological significance. It is clear from the instant specification that the claimed novel nucleic acid encodes "a novel splice variant of the Golf G protein referred to herein as XLGolf" (page 5of the instant specification). The specification discloses the structure of XLGolf as SEQ ID NO: 2 encoded by the polynucleotide of SEQ ID NO: 1. At pp. 2-3, it is stated that the novel splice variant of XLGolf displays structural similarity to the GNAL genes, which are described in the literature as being mapped to the chromosomal regions associated with frequency of schizophrenia and bipolar affective disorder. The specification does not disclose any specific biological role of the instant XLGolf polypeptide of SEQ ID NO: 2, or its particular association with a pathological condition or physiological process.

In the absence of knowledge of the biological significance of this specific nucleic acid and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. According to the specification of the instant application, "[m]easuring Golf and XLGolf expression in tissues from patients will be useful to predict susceptibility to disease and/or response to treatment" (page 21). However, the instant specification fails to provide any

evidence or sound scientific reasoning that would support a conclusion that the instant nucleic acid or encoded protein is associated with any diseases or disorder. There are no data to support use of the polynucleotide of SEQ ID NO: 1 as a diagnostic, as asserted by the specification – "Golf and XLGolf protein expression could also be measured as a diagnostic", p. 21. To employ the XLGolf DNA or its encoded protein in the screening methods to look for modulators of their interactions with different GPCRs, see pp. 22-23 of the specification, is not a "real world" because it would eventually relate to a protein for which no biological function is known.

Because the instant specification does not teach a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the administration of a compound that "modulate[s] the interaction between Golf/XLGolf and a selected GPCR" would prevent or treat a condition or disease, like schizophrenia or bipolar affective disorder, as implied by the specification. To employ a nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the XLGolf nucleic acids or their encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-6 and 9-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. Claims 1, 3-6, 9 and 11 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 9 and 11 encompass polynucleotides and polypeptides having at least 80% or 85% sequence identity with a particular disclosed sequence. The claims do not require that the claimed nucleic acids or polypeptide possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids and polypeptides that is defined only by sequence identity. However, the instant specification fails to describe the entire genus of nucleic acids, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 2. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO: 1. The claims encompass nucleic acids and proteins having at least 80% or 85% sequence identity with the disclosed SEQ ID NO: 1 and SEQ ID NO: 2. Thus, the claims are not limited to a nucleic acids with a specific nucleic acid sequence. The claims only require the claimed nucleic acids to share

some degree of structural similarity to SEQ ID NO: 1. The specification only describes an nucleic acid having the sequence of SEQ ID NO: 1 and the sequence encoding polypeptide of SEQ ID NO: 2 and fails to teach or describe any other nucleic acid which lacks these structures and has any relevance to XLGolf polypeptide.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Moreover, as stated above, it is not even clear what is the biological activity of XLGolf protein. The specification does not provide a complete structure of those polynucleotides having at least 85% sequence identity with a nucleic acid of SEQ ID NO: 1 and fails to provide a representative number of species for the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at

page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids comprising SEQ ID NO: 1 or encoding polypeptide of the amino acid sequence set forth in SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

> international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 3-6, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 7,371,541, filing date of 07/11/2003, '541 patent from hereafter.

Claims 1, 3-6, 9 and 11 are directed to isolated nucleic acid molecules comprising polynucleotide sequence of at least 85% sequence identity to SEQ ID NO: 1, vectors, host cells and methods of recombinant polypeptide production. '541 patent teaches polynucleotide sequence of SEQ ID NO: 2, which has 99.8% sequence identity with the instant polynucleotide of SEQ ID NO: 1, see sequence alignment attached to the instant office action. Further, the '541 document teaches method of polypeptide production, which includes vectors, host cells and the process itself, thus fully anticipating the instant claimed invention.

Conclusion

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

March 19, 2009

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649